MEASUREMENT ASSURANCE FOR CELL THERAPY WORKSHOP
DAY 2 AGENDA

9:00 – 9:10: Sheng Lin-Gibson (Deputy Chief, Biosystems & Biomaterials Division), Welcome back

9:10 – 10:40: Full reports from breakouts showing cause and effects diagrams, flow charts, needs for reference materials, potential for inter-laboratory studies, etc.

- 9:10 – 9:40: Breakout#1 Report: Cell Counting
- 9:40 – 10:10: Breakout #2 Report: Cell Viability
- 10:10 – 10:40: Breakout #3 Report: Functional Cell Assay

10:40 – 11:00: Coffee Break

11:00 – 12:00: Panel Discussion; Moderator: Carl Simon

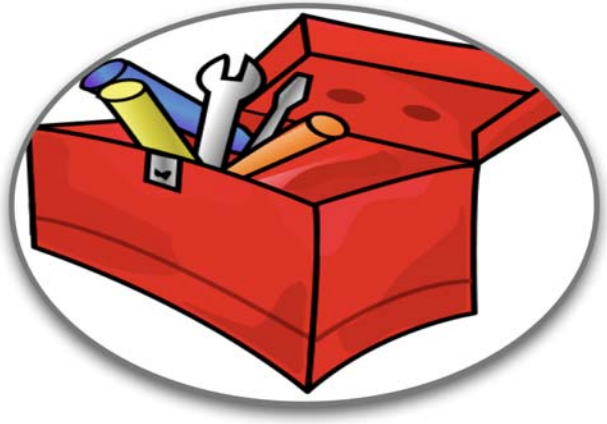
12:00 – 12:15: Concluding remarks

RECAP OF DAY 1

Tools for achieving **measurement assurance/confidence** for **measurement process**

- Traceability
- Measurement uncertainty
- Method validation

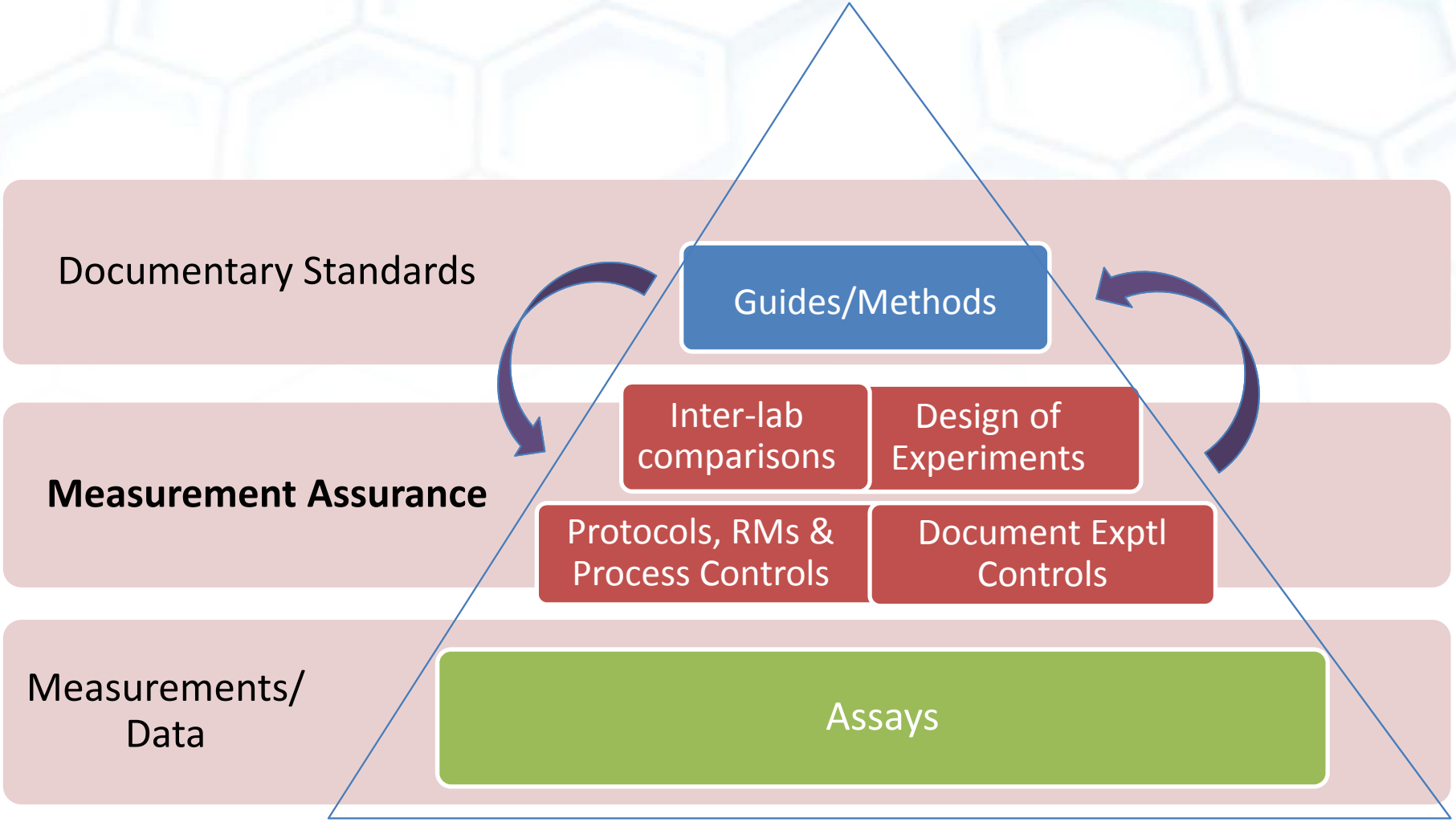
- Reference materials or controls
- Ishikawa (cause/effect) diagram
- Charting
- Process controls
- Experimental Design
- Quality by Design (QbD)
- Validation specifications
- Interlaboratory comparison



RECAP OF DAY 1

- Case study of specific assays
  - Cell counting
  - Viability
  - Functional assay

The process of developing a standard is founded on measurement assurance



- Facilitate regulatory approval and commerce
- Broadly applicable
- Do not impede innovation

Standards Efforts for Cell Therapy

Many on going efforts, include several that aims to develop standard methods

http://www.nist.gov/mml/bbd/iso.cfm

Contacts: slgibson@nist.gov

ISO/TC 276: Biotechnology

Secretariat: DIN

Secretary: Katharina Lippert

Chairperson: Ricardo Gent

22 participating countries

13 observing countries

Structure:

Terms and Definition

Biobanking and Bioresources

Analytical Methods

Bioprocessing

Data Processing and Integration

U.S. TAG for ISO/TC 276

Secretariat: NIST

TAG Administrator: Clare Allocca

Chairperson: Sheng Lin-Gibson

46 Organizations

96 Individuals

Structure:

Terms and Definition

Biobanking and Bioresources

Analytical Methods

Bioprocessing

Data Processing and Integration

CELL COUNTING STANDARDS

Industry needs:

- Cell type independent
- Measurement platform independent
- Amenable to changes in measurement process

Proposed solutions:

- An approach to assess the **measurement confidence** for a specific cell count measurement process where a reference material is not readily available

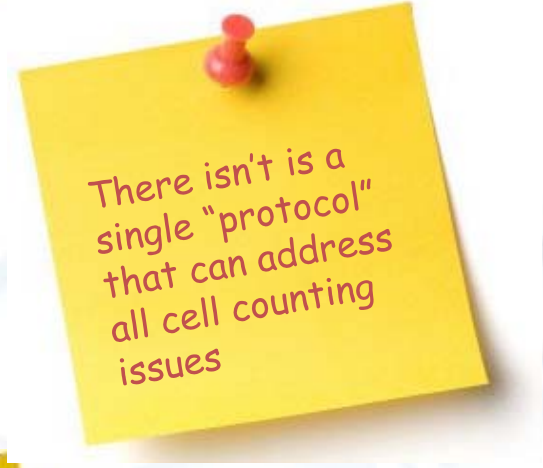
OVERALL CELL COUNTING STANDARDIZATION STRATEGY

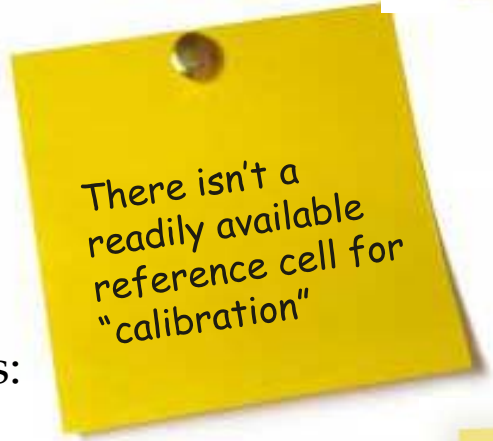
Part 1: General Guidance on cell counting methods

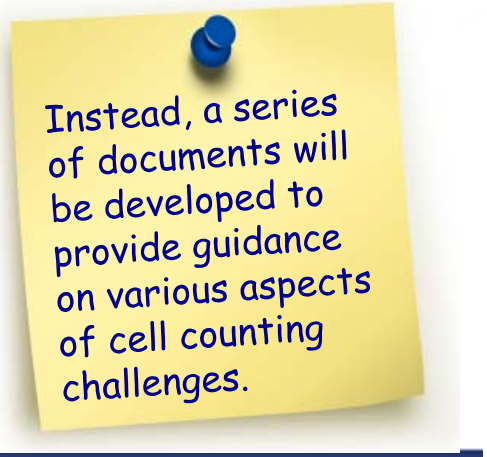
Part 2: Experimental design and statistical analysis to quantify counting method performance

Part 3 and above or independent standards:

- Application of reference materials and benchmarks
- Differential cell counting methods, i.e., viable cell counting
- Method to address morphology or manufacturing processes







CURRENT ISO/TC 276 WORK RELATED TO CELL THERAPY

WG3: Analytical Methods

ISO/PWI 20391: *Methods to determine a relative accuracy for cell counting approaches*

ISO/PWI 20395: *Quality considerations for targeted nucleic acid quantification methods*

ISO/PWI 20396: *Methods to determine the concentration of total nucleic acids*

ISO/PWI 20397: *Methods to evaluate the quality of the massive sequencing data*

ISO/PWI 20688: *Oligonucleotide Quality Control*

New project *to develop a standard for cell viability*

New project *to develop a stratagy to develop cell characterization standards*

WG4: Bioprocessing

ISO/PWI 20398: *Methods to control bioreactor processes for cell culturing*

ISO/PWI 20399: *Raw materials control for bioprocessing*

ISO/PWI: *Best practice in raw materials selection in the design of human cell therapy 1. manufacturing processes*

GOALS FOR DAY 2

Report of findings from breakout sessions

- Common measurement challenges, including sources of variability
- Potential solutions using tools to achieve measurement assurance

Panel Discussion

- What can we do collectively to improve the measurement confidence of common assays?

NEXT STEPS

Are there interests to continue discussions/ work to achieve measurement assurance for cell therapy?

If so,

- What are the desirable outcomes?
- What is the most effective forum?
- Who else should be a part of this discussion?

OPTIONS

Forum for next steps

- NIST-convened continuing discussions on measurement assurance for cell therapy
- Working Groups to develop specific protocol/best practices

Potential Products

- Training materials
- White papers
- Shared protocols and/or best practices
- Standards
    - Reference materials
    - Consensus documentary standards

REPORTS FROM BREAKOUTS

9:10 – 9:40: Cell Counting

9:40 – 10:10: Cell Viability

10:10 – 10:40: Functional Cell Assay